United States Court of Appeals

for the Second Circuit

REPLY BRIEF

76-1398

To be argued by
COPAL MINTZ

B
P/S

United States Court of Appeals

FOR THE SECOND CIRCUIT

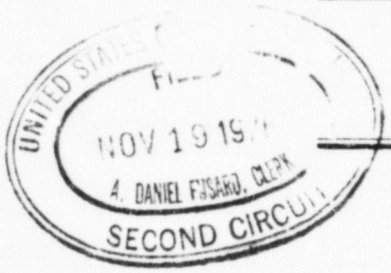
Docket No. 76-1398

UNITED STATES OF AMERICA,
Plaintiff-Appellee,

—against—

DIAPULSE CORPORATION OF AMERICA, also known as THE DIAPULSE MANUFACTURING CORPORATION OF AMERICA, a corporation, JESSE ROSS, President of the corporation and JOSEPH I. ROSS, Vice-President and Treasurer of the corporation,
Defendants-Appellants.

ON APPEAL FROM THE UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF NEW YORK



DEFENDANTS-APPELLANTS' REPLY BRIEF

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UNITED STATES COURT OF APPEALS
FOR THE SECOND CIRCUIT

- -X

UNITED STATES OF AMERICA,

Plaintiff-Appellee,

-against-

DIAPULSE CORPORATION OF AMERICA, etc.,

Defendants-Appellants.

- -X

APPELLANTS' REPLY BRIEF

Counsel for Appellants respectfully submits that the seven authors of Appellee's Brief have shied away from addressing themselves to the crux of the case.

(1). The authority certified by FD Form 200C (which Appellee quotes on page 12 of its brief and which is quoted on page 5 of Appellants' Brief) is only to "have access to and copy or verify any records and reports required under Section 505(i) or (j) or 507(d) or (g) of the Federal Food, Drug and Cosmetic Act'.

Those sections (21 U.S.C. 355(1) and (j) and 21 U.S.C. 357(d) and (g)) deal with and apply only to "new drugs". Thus, they have no bearing whatsoever on devices and no bearing whatsoever on the injunction -- other than to negate authority or authorization to inspect defendants' premises and the contents thereof.

The additional authorizations to administer oaths, etc., which Appellee italicizes, manifestly are only ancillary to the specified authority in respect to new drugs; they cannot reasonably be viewed as an unlimited delegation "to act for the Commissioner in the performance of the duties provided in the laws and Department Regulations administered by the Food and Drug Administration". The injunction could not enlarge the agency's powers.

(2). Similarly, Appellee's quotation (on page 11) from the Regulations relate only to "enforcement of the Federal Food, Drug and Cosmetic Act." And Form 200C, which the inspectors exhibited, limited further their authority to inspections relating to 'new drugs'.

Thus 'duly authorized officers and employees of the Food and Drug Administration" necessarily means FDA officers or employees who are 'duly authorized" under and in accordance with the statute and Regulations which govern the FDA. Neither the statute nor the Regulations provide for the vesting of authority in any officer or employee of the FDA to make other investigations.

It is not enough that inspectors are 'duly authorized officers and employees of the Food and Drug Administration'; they must be officers or employees of the Food and

Drug Administration who are "duly authorized" to make the inspection specified in the injunction and such special authority must be exhibited to those of whom access is demanded.

The injunction did not mandate or direct the FDA to inspect, etc. If the agency, under the statute and its Regulations, had no power to avail itself of Section V(B) of the injunction, it had to forego it.

Indeed, since the injunction did not apply to devices for export, such devices and their components were not 'prohibited devices' and were not of any concern to the FDA.

(3). What is said above applies to 21 U.S.C. 374(a). It does not provide, as Appellee asserts on page 14, "general authority for inspections for the enforcement of the Food and Drug Act". On the contrary, the authority is <u>specific and limited</u> (see pages 6-7 of Appellants' Brief). Inspection may be made only "upon presenting appropriate credentials and a written notice to the owner, operator or agent in charge" and, in respect to devices, only in establishments in which devices "are manufactured, etc., for introduction into Interstate Commerce or after such introduction" and only to inspect the establishment "and all pertinent equipment, finished and unfinished materials, containers and labeling therein". Nothing beyond that.

(4). Judge Dooling has made clear the necessary differentiation between inspection under 21 U.S.C. 374(a) and inspection under Section V(B) of the injunction. Appellee's Brief ignores that.

If the FDA believed that it had a right to disregard the limitations of the statute and the Regulations and its established forms, it could very simply have prepared a notice addressed to the defendants reading substantially as follows:

> Notice is hereby given that Bearer , upon exhibiting to you his identification certificate and delivering to you this Notice, is authorized and directed, pursuant to paragraph V(B) of the judgment of injunction dated July 18, 1974, in the action in the United States District Court, Eastern District of New York, entitled United States of America, Plaintiff, v. Diapulse Corporation of America, et al, defendants, to have access to your offices, plants, factories, warehouses, storage facilities or other establishments, and to inspect the same and their contents, and make copies, to the full extent set forth in said Section V(B) which reads as follows: [Section quoted]. Failure to comply will render you liable to prosecution for contempt of court and the penalties prescribed by law. Dated and signed by the Commissioner of Food and Drugs .

That would have accomplished the 'clear-cut manifestation" which Judge Dooling held was indispensable and would have avoided 'a confusing and wholly inappropriate intrusion".

(5). The teletypes (Appx. Pages 32-38) were admitted erroneously because: (i) They purported to be from the "Division of Compliance HFK-100"; two of them were signed by Michael J. Matlock and one by Dan R. Beardsley; no evidence was adduced of their authority; an attorney who described himself as 'an attorney in the office of General Counsel of Health, Education and Welfare in the Food and Drug Administration" and who had been active in the litigation with the defendants (Appx. Pages 262-264, 267) could say no more than that Mr. Matlock "was a Compliance Officer" whose 'exact technical title" he did not know and that Mr. Beardsley "was in the same area" whose "exact title" he was not sure of (Appx. Page 270); (ii) They were not exhibited to the defendants nor were they informed thereof; the credentials which the inspectors exhibited bore the Commissioner's name; the printed notice which they delivered to defendants obviously was official; the claimed secret superseding teletypes did not have such legitimacy.

Plainly, disclosure in a bill of particulars, four months after the event, did not render them admissible.

(6). The introduction of the testimony regarding the July 2, 1975 episode (which the court held did not result in a basis for a contempt charge) had no discernible raison detre other than to prejudice the defendants.

(7). The other claimed errors, it seems to Appellants' counsel, do not require elaboration.

(8). The foregoing, of course, is by way of supplement to Appellants' Brief -- not in substitution for any part thereof.

Respectfully submitted,

COPAL MINTZ,
Attorney for Defendants-Appellants.

Dated: November 19, 1976.

Paula
Jardine